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| APPLICATION NO.                  | FILING DATE                       | FIRST NAMED INVENTOR          | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-----------------------------------|-------------------------------|---------------------|------------------|
| 10/578,850                       | 04/06/2007                        | Bruno Tse                     | APX0028-501-US      | 5044             |
|                                  | 7590 01/19/201<br>ENT GROUP - APX | EXAMINER                      |                     |                  |
| 1005 North Wa                    |                                   | BALASUBRAMANIAN, VENKATARAMAN |                     |                  |
| Suite 201<br>ST. LOUIS, MO 63132 |                                   |                               | ART UNIT            | PAPER NUMBER     |
|                                  |                                   |                               | 1624                |                  |
|                                  |                                   |                               |                     |                  |
|                                  |                                   |                               | NOTIFICATION DATE   | DELIVERY MODE    |
|                                  |                                   |                               | 01/19/2011          | ELECTRONIC       |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|  | Application No.   | Applicant(s) |  |  |  |
|--|---|--------------|--|--|--|
|  | 10/578,850  | TSE ET AL.   |  |  |  |
| Office Action Summary  | Examiner  | Art Unit     |  |  |  |
|  | /Venkataraman<br>Balasubramanian/   | 1624         |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |              |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |
| Status   |   |              |  |  |  |
| 1) Responsive to communication(s) filed on 10 M  | lay 2006.   |              |  |  |  |
|  | action is non-final.  |              |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |   |              |  |  |  |
| Disposition of Claims  |   |              |  |  |  |
| 4) Claim(s) 1-19 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) is/are allowed.  6) Claim(s) is/are rejected.  7) Claim(s) is/are objected to.  8) Claim(s) 1-19 are subject to restriction and/or election requirement.  |   |              |  |  |  |
| Application Papers   |   |              |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |              |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |              |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |              |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |              |  |  |  |
| Priority under 35 U.S.C. § 119   |   |              |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |              |  |  |  |
| Attachment(s)  |   |              |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>   | 4) Interview Summar<br>Paper No(s)/Mail D<br>5) Notice of Informal<br>6) Other: | Date         |  |  |  |

## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-14, drawn to compound of formula A wherein X is O and  $R_5$  is a pyrimidine base not fused with any ring shown in claim 2, composition and method of use.

Group II, claims 1-14, drawn to compound of formula A wherein X is O and  $R_5$  is a fused pyrimidine base shown in claim 2, composition and method of use.

Group III, claims 1-14, drawn to compound of formula A wherein X is O and  $R_5$  is a triazole base shown in claim 2, composition and method of use.

Group IV, claims 1-14, drawn to compound of formula A wherein X is S and  $R_5$  is a pyrimidine base not fused with any ring shown in claim 2, composition and method of use.

Group V, claims 1-14, drawn to compound of formula A wherein X is S and  $R_5$  is a fused pyrimidine base shown in claim 2, composition and method of use.

Group VI, claims 1-14, drawn to compound of formula A wherein X is S and  $R_5$  is a triazole base shown in claim 2, composition and method of use.

Group VII, claims 1-14, drawn to compound of formula A wherein X is  $NR_6$  and  $R_5$  is a pyrimidine base not fused with any ring shown in claim 2, composition and method of use.

Group VIII, claims 1-14, drawn to compound of formula A wherein X is  $NR_6$  and  $R_5$  is a fused pyrimidine base shown in claim 2, composition and method of use.

Group IX, claims 1-14, drawn to compound of formula A wherein X is  $NR_6$  and  $R_5$  is a triazole base shown in claim 2, composition and method of use.

Group X, claims 1-14, drawn to compound of formula A, composition and method of use. If this Group is elected applicants should also elect a specific X and Specific R<sub>5</sub> not provided in the above Groups I-IX for examination.

Group XI, claims 15-17, drawn to a method for modulating the expression of enzymes, proteins, nuclear factors or receptors in cells or tissues comprising contacting the cells or tissues with at least one compound of claims 1-10 and treating a disease or condition thereby. If this Group is elected applicants should also elect a specific X and specific  $R_5$  either from Group I-IX or not provided in the above Groups I-IX for examination.

Group XII, claims 18 and 19, drawn to a nucleic acid probe constructed from at least one compound of formula A of claim1 and method of use of the nucleic acid probe. If this Group is elected applicants should also elect a specific X and specific R<sub>5</sub> either from Group I-IX or not provided in the above Groups I-IX for examination.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Where there is lack of unity the requirement for restriction is proper- See MPEP 803.02. The requirement for unity of invention is two-fold: (1) common utility and (2) sharing a substantial structural feature disclosed as being essential to the utility. Both these conditions are to be met with. Instant claims do not meet both these conditions.

Invention I, II, III, IV, V, VI, VII, VIII, IX, X, XI and XII are independent and distinct from each other because they are directed to structurally dissimilar compounds that lack common core, namely, various heterocyclic groups besides pyrimidinyl, fused pyrimidinyl and triazolo cores for A choices. Consequently, the groups require separate prior art searches. They can be made and used independently. Art which may render obvious or anticipate one of the groups would not necessarily do the same for the other group. For example prior art cited in the International Search Report and the Information Disclosure Statement may not be applicable to all the above groups. Each can support a patent as the compounds of each group are capable of being utilized alone not in combination with other members listed in the Markush group.

Except for the 6-memebered heterocyclic core bearing O, S and N group, every ring and substituents in the core of compound of formula A is varied and it cannot be said that a six-membered ring bearing O, S or N atom essentially contribute to the utility recited in the claims. Thus, the common structural feature essential for the said utility is not met with.

In addition, common utility requirement is also not met with as evident from the claims that these compounds can be used for treating various cancers, modulating the expression of enzymes, proteins, nuclear factors or receptors in cells or tissues and thereby treating any or all diseases and conditions as well as use of the compounds as nucleic acid probes and for diagnosis of bacterial infections. In addition, prior art cited in the Information Disclosure Statement and International search report clearly state other uses for the instant compounds. Thus, both the criteria set forth for unity of invention is not met with.

In view of distinct nature of each invention, the restriction requirement is set forth in writing.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

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(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624